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C O N F I D E N T I A L SECTION 01 OF 02 TAIPEI 002078

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STATE FOR EAP/RSP/TC, STATE PASS AIT/W AND USTR FOR KI AND FREEMAN, USDOC FOR 4431/ITA/MAC/AP/OPB/TAIWAN/MBMORGAN AND JDUTTON

E.O. 12958: DECL: 05/05/2015
TAGS: ECON ETRD TW
SUBJECT: PHARMACEUTICAL VALIDATION: A METHOD? OR MORE MADNESS?

Classified By: AIT Director Douglas Paal, Reason 1.4 (b)

¶1. (U) Summary: Representatives from PhRMA accompanied AIT to meetings with Taiwan Department of Health (DOH) officials to discuss pharmaceutical validation issues on April 28. AIT intervention salvaged a heated exchange between PhRMA, Taiwan,s Bureau of Food and Drug Analysis (BFDA) and local pharmaceutical association representatives. BFDA's Risk Profile Number (RPN) methodology continues to lack transparency but the meeting eventually led to promises of useful clarifications of terms. A brief discussion of BFDA proposed computer validation requirements reassured PhRMA that Taiwan's requirements should not be too difficult to meet. In a separate meeting, Taiwan,s Bureau of Pharmaceutical Affairs (BOPA) agreed to allow PhRMA to provide input into the draft guidelines for review of Active Pharmaceutical Ingredients (API) and agreed to extend import licenses for medical devices in the registration process until the end of 2005. End Summary.

¶2. (U) In response to a request by the Pharmaceutical Research Manufacturers Association (PhRMA) and the International Research Pharmaceutical Manufacturers Association (IRPMA), Acting Director General of Taiwan,s BFDA, Erick Suen called a meeting of pharmaceutical manufacturers to discuss outstanding validation issues including the methodology for assigning RPNs and requirements for computer validation. Cynthia Wang (Merck), Allan Chu (Eli Lilly), Roy von Kutzleben (Pfizer), and Marie Vodicka (PhRMA), joined IRPMA's Executive Director Carol Cheng and AIT Econ and Commercial officers in attending.

BFDA Wants an RPN Resolution Now

¶3. (SBU) Acting DG Suen was eager to reach consensus on acceptable RPN methodology, used to identify pharmaceutical manufacturing sites for inspection by Taiwan authorities. PhRMA was not prepared to agree to any particular formulations but raised several questions about the apparent arbitrariness of the scoring and weighting of each factor in the formula. BFDA attempted to negotiate the scoring of each factor and was extremely frustrated by PhRMA's reluctance to bargain. After a brief break that allowed participants to disengage and consult among themselves, Suen returned and agreed to hear PhRMA's concerns without insisting on negotiating compromises in the meeting.

¶4. (U) BFDA's RPN formula considers four categories: quality control issues, dosage forms, a Good Manufacturing Process (GMP) Standard and Regulatory Environment, and the volume of product distributed in Taiwan. These scores are weighted and totaled and then used to prioritize manufacturing site inspections. PhRMA expressed no concerns about scoring or weighting in the dosage form or volume categories, but had concerns about the definitions and weighting in the quality control and regulatory environment categories.

PhRMA Asks for Clarifications on RPN Categories

¶5. (U) Specifically, PhRMA asked for clarification about the criteria for determining the pharmacovigilance score (based on BFDA's post-marketing surveillance and distributor complaints) and a vaguely worded catchall category for "special situations." PhRMA also requested clarifications on scoring for those companies that had products recalled. BFDA responded that the score could be differentiated based on whether the recall was government mandated or self-initiated and whether the recall was for quality or safety issues.

¶6. (U) PhRMA also disagreed with the scoring based on the regulatory environment of the manufacturing country and differential based on the type of documentation provided (full documents vs. the Certificate of Pharmaceutical Product (CPP) and template), arguing that these factors were

inappropriately scored and violated BFDA's commitment to ensure that the RPN factors would be risk based. BFDA countered that a manufacturer's willingness to submit full documentation was a show of compliance with Taiwan regulations and should be rewarded, an argument that was quickly rejected by AIT and PhRMA. BFDA agreed to provide more detailed explanations of each factor and post them on the BFDA website.

¶7. (U) Finally, AIT and PhRMA raised questions about the weighting for each category. Due to simple mathematical errors, it appears BFDA's formula unintentionally over weights the first category. BFDA confirmed its intention is to weight each category as a fixed percentage of the final score and promised to review the math.

Computer Validation Too Easy?

¶8. (U) Discussion of computer validation (stage three) procedures focused on BFDA's creation of a detailed draft checklist. PhRMA expressed concern that the checklist it had seen was too detailed and suggested that it would be impossible for manufacturers to complete. AIT urged BFDA to remain consistent with the principles of stage one and two validation and minimize additional required documentation. BFDA clarified that the checklists were being drafted as an internal tool only and that manufacturers would not be required to submit these documents. Suen and his staff agreed that a description and overview of computer systems already validated by a competent national authority should meet Taiwan's requirement. BFDA also requested that PhRMA prepare a concrete proposal for computer validation requirements and confirmed that it would be willing to accept any CPP that includes a GMP certificate issued after computer certification had been included in the GMP process as fulfillment of this requirement. BFDA also reminded PhRMA that manufacturers that volunteer for inspection are exempt from these requirements.

BOPA Raises GMP-API

¶9. (U) Separately, the PhRMA delegation paid a courtesy call on Counselor to the Minister of Health, Dr. Hsiao Mei-ling, and BOPA Director General Dr. Wang Hui-po. Hsiao and Wang again confirmed that BFDA is the competent Taiwan authority for all matters related to pharmaceutical validation. They also raised the issue of BOPA's review of active pharmaceutical ingredients (API), explaining that API reviews are conducted by a BOPA-assigned committee. PhRMA noted that it may not be possible for all manufacturers to provide requested GMP-API documents since each country has differing requirements. BOPA agreed to consider any input from PhRMA as the guidelines are being drafted.

Good News on Registrating Medical Devices

¶10. (U) AIT Econoff took the opportunity to raise a separate issue regarding registration of medical devices. Manufacturers and importers are being required to register all classes of medical products by June 20, 2005 or face import restrictions. Manufacturers and importers have expressed concern that BOPA staff will be unable to process registration applications by the deadline, potentially barring life-saving devices from Taiwan. BOPA DG Wang said BOPA recognized the problem and had decided that as long as manufacturers submitted registration applications by the June 20 deadline, they would not face import restrictions through the end of 2005.

Comment: PhRMA Hurting Itself

¶11. (C) Comment: PhRMA's frustrating meeting with BFDA was in significant part a result of PhRMA's lack of coordination either with BFDA or AIT. PhRMA informed AIT less than a week before the delegation was scheduled to arrive and made no effort to involve AIT in scheduling of meetings or setting of agendas. The parties had widely divergent expectations for the meeting and it was only the timely intervention of AIT officials that allowed the parties to return to the table for what ended up being moderately productive discussions. The most significant obstacle to progress in resolving pharmaceutical validation issues has been a lack of reliable communication between Taiwan,s DOH and PhRMA, all too often the origin of the problem has been disorganization and an inability or unwillingness to coordinate on PhRMA's part. The remaining technical issues involved with RPN calculation may require some compromise but should not be too difficult to resolve. To do so, however, will require vastly improved

coordination and communication between PhRMA, AIT and BFDA.
AIT made this point clearly to PhRMA delegates and it
appeared to be understood before they departed.
PAAL